

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

CHRISTINE LAVORE,

Plaintiff,

v.

BOSTON SCIENTIFIC CORP.,

Defendant.

No. 4:20-CV-00780

(Judge Brann)

MEMORANDUM OPINION

JUNE 25, 2020

I. BACKGROUND

This case used to be part of Multi District Litigation No. 2326: the Boston Scientific Corp. Products Liability Litigation. After Plaintiff Christine Lavore’s individual case neared conclusion, the Honorable Joseph R. Goodwin, United States District Judge for the Southern District of West Virginia, transferred Lavore’s case here “[f]or the convenience of the parties and in order to promote [its] final resolution.”¹

Part of the “final resolution” is Boston Scientific Corporation’s ripe Motion for Summary Judgment.² Boston Scientific requests summary judgment on Lavore’s claims for strict liability (Counts II-IV),³ breach of express warranty

¹ Doc. 55 at 1. This case’s original docket number is 2:13-cv-21153. *See* Doc. 55 Ex. A.

² Doc. 50.

³ Lavore brings separate strict liability claims under theories of design defect (Count II), manufacturing defect (Count III), and failure to warn (Count IV).

(Count V), breach of implied warranty (Count VI), and fraudulent concealment (Count VIII).⁴

Lavore does not contest Boston Scientific's request for summary judgment on Counts III, V, VI, and VIII.⁵ But a "district court must conduct a merits analysis of the moving party's motion even in the absence of opposition."⁶ Therefore, the Court considers and discusses below all the areas in which Boston Scientific seeks summary judgment.

The Court grants Boston Scientific's motion in part and denies it in part.

II. DISCUSSION

A. Standard of Review

I begin my analysis with the standard of review which undergirds summary judgment. "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses, and we think it should be interpreted in a way that allows it to accomplish this purpose."⁷ Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."⁸ "Facts that could alter the outcome are 'material facts,' and

⁴ Doc. 50 at 1. All Count references are to Plaintiffs' Master Complaint, which is docketed in this case at Doc. 56-4.

⁵ Doc. 52 at 1-2.

⁶ *Good-O Beverage, Inc. v. Lion Brewing Co.*, No. 3:09-CV-800, 2010 WL 11678256, at *1 (M.D. Pa. Nov. 17, 2010), *adhered to on reconsideration*, No. 3:09-CV-800, 2010 WL 11678257 (M.D. Pa. Dec. 8, 2010)

⁷ *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986).

⁸ Fed. R. Civ. P. 56(a).

disputes are ‘genuine’ if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct.”⁹ “A defendant meets this standard when there is an absence of evidence that rationally supports the plaintiff’s case.”¹⁰ “A plaintiff, on the other hand, must point to admissible evidence that would be sufficient to show all elements of a *prima facie* case under applicable substantive law.”¹¹

“The inquiry involved in a ruling on a motion for summary judgment or for a directed verdict necessarily implicates the substantive evidentiary standard of proof that would apply at the trial on the merits.”¹² Thus, “if the defendant in a run-of-the-mill civil case moves for summary judgment or for a directed verdict based on the lack of proof of a material fact, the judge must ask himself not whether he thinks the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented.”¹³ “The mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.”¹⁴ “The judge’s inquiry, therefore, unavoidably asks . . . ‘whether there is [evidence] upon which a jury can properly

⁹ *Clark v. Modern Grp. Ltd.*, 9 F.3d 321, 326 (3d Cir. 1993) (Hutchinson, J.) (*citing Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) and *Celotex*, 477 U.S. at 322).

¹⁰ *Clark*, 9 F.3d at 326.

¹¹ *Id.*

¹² *Liberty Lobby, Inc.*, 477 U.S. at 252.

¹³ *Id.*

¹⁴ *Id.*

proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed.”¹⁵ The evidentiary record at trial, by rule, will typically never surpass that which was compiled during the course of discovery.

“A party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.”¹⁶ “Regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c), is satisfied.”¹⁷

Where the movant properly supports his motion, the nonmoving party, to avoid summary judgment, must answer by setting forth “genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.”¹⁸ For movants and nonmovants alike, the assertion “that a fact cannot be or is genuinely disputed” must be supported by:

(i) “citing to particular parts of materials in the record” that go beyond “mere allegations”; (ii) “showing that the materials cited do not establish the absence or

¹⁵ *Id.* (quoting *Schuylkill & Dauphin Imp. Co. v. Munson*, 81 U.S. 442, 447 (1871)).

¹⁶ *Celotex*, 477 U.S. at 323 (internal quotations omitted).

¹⁷ *Id.*

¹⁸ *Liberty Lobby*, 477 U.S. at 250.

presence of a genuine dispute”; or (iii) “showing . . . that an adverse party cannot produce admissible evidence to support the fact.”¹⁹

“When opposing summary judgment, the non-movant may not rest upon mere allegations, but rather must ‘identify those facts of record which would contradict the facts identified by the movant.’”²⁰ Moreover, “if a party fails to properly support an assertion of fact or fails to properly address another party’s assertion of fact as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion.”²¹ On a motion for summary judgment, “the court need consider only the cited materials, but it may consider other materials in the record.”²²

Finally, “at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.”²³ “There is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party.”²⁴ “If the evidence is merely colorable . . . or is not significantly probative, summary judgment may be granted.”²⁵

¹⁹ Fed. R. Civ. P. 56(c)(1).

²⁰ *Port Auth. of N.Y. and N.J. v. Affiliated FM Ins. Co.*, 311 F.3d 226, 233 (3d Cir. 2003) (Weis, J.).

²¹ Fed. R. Civ. P. 56(e)(2).

²² Fed. R. Civ. P. 56(c)(3).

²³ *Liberty Lobby*, 477 U.S. at 249.

²⁴ *Id.*

²⁵ *Id.* at 249-50 (internal citations omitted).

B. Undisputed Facts

With that standard outlining the Court's framework for review, I now turn to the undisputed facts of this matter.

Lavore is a citizen and resident of New York State.²⁶ On January 11, 2013, Lavore underwent an Obtryx Transobturator Mid-Urethral Sling System ("Obtryx") procedure performed by Dr. Lee Herbst at the Robert Packer Hospital in Sayre, Bradford County, Pennsylvania.²⁷ The Obtryx was implanted to treat Lavore's stress urinary incontinence.²⁸

In 2004, the Food and Drug Administration had cleared Boston Scientific to market the Obtryx device as described in Boston Scientific's Section 510(k) premarket notification.²⁹ The Obtryx is a medical device implanted during surgery by a physician and is available by prescription only.³⁰

Lavore has alleged that, due to the implantation of the Obtryx, she has suffered chronic leg pain, nerve damage, groin pain, bladder bleeds, muscle spasms, removal surgeries, inability to walk, and painful intercourse.³¹ Lavore directly filed this product liability action against Boston Scientific in Multi District Litigation No. 2326 on July 29, 2013.³² Lavore asserts claims for negligence, strict

²⁶ Doc. 50, Statement of Facts at ¶ 1.

²⁷ Doc. 50, Statement of Facts at ¶ 2.

²⁸ Doc. 50, Statement of Facts at ¶ 3.

²⁹ Doc. 50-3.

³⁰ Doc. 50, Statement of Facts at ¶ 5.

³¹ Doc. 50, Statement of Facts at ¶ 6.

³² Doc. 50, Statement of Facts at ¶ 7.

liability (under theories of design defect, manufacturing defect, and failure to warn), breach of express warranty, breach of implied warranty, and fraudulent concealment.³³

C. Lavore's Strict Liability Claims

Federal district courts in Pennsylvania differ on whether to bar strict liability claims as a categorical matter of law when plaintiffs assert these claims against producers of prescription medical devices.³⁴ Though this is a difficult decision,³⁵ I find the Honorable Gerald J. Pappert's reasoning in a recent decision, *Ebert v. C.R. Bard, Inc.*, No. CV 12-01253, 2020 WL 2332060, at *9-*10 (E.D. Pa. May 11, 2020), quite persuasive. I adopt Judge Pappert's reasoning here.

In short: first, the 2006 Pennsylvania Superior Court decision *Creazzo v. Medtronic, Inc.*,³⁶ which district courts often rely on to predict a categorical ban, is "supported by scant reasoning and in the fourteen years since *Creazzo*, the Pennsylvania Supreme Court has not relied on it."³⁷ This makes *Creazzo*, in this Court's eyes, not very persuasive. Second, two 2014 Pennsylvania Supreme Court decisions,³⁸ "taken together, undermine *Creazzo*'s persuasive force and suggest

³³ Doc. 50, Statement of Facts at ¶ 8.

³⁴ The Honorable Jeffrey L. Schmehl discusses the two different stances in a somewhat recent decision, *Wilson v. Synthes USA Prod., LLC*, 116 F. Supp. 3d 463, 466 (E.D. Pa. 2015).

³⁵ The Pennsylvania Supreme Court has not provided express guidance on this issue.

³⁶ 903 A.2d 24 (Pa. Super. Ct. 2006).

³⁷ *Ebert v. C.R. Bard, Inc.*, No. CV 12-01253, 2020 WL 2332060, at *10 (E.D. Pa. May 11, 2020).

³⁸ See *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 396 (Pa. 2014); *Lance v. Wyeth*, 85 A.3d 434, 454 (Pa. 2014).

that the Pennsylvania Supreme Court would not apply comment k [of the Restatement (Second) of Torts] to categorically exempt all prescription medical devices from strict liability claims.”³⁹ Based on the above, this Court “predicts that the Pennsylvania Supreme Court would not categorically [bar strict liability claims against] all prescription medical device manufacturers. Rather, the Court predicts that Pennsylvania’s highest court would instead analyze [strict liability’s] applicability to prescription medical devices on a case-by-case basis, determined largely by each case’s developed factual record and the individual characteristics of the medical device at issue.”⁴⁰

Here, based on the evidence before the Court, I cannot conclude that the Obtryx device is an “unavoidably unsafe product,” such that the Pennsylvania Supreme Court would apply comment k of the Restatement (Second) of Torts to the Obtryx and therefore shield Boston Scientific from Lavore’s strict liability claims. As one example, the Food and Drug Administration certified the Obtryx device as regulatory “class II (Special Controls).”⁴¹ Federal statute provides that for this class of device, “there is sufficient information to establish special controls to provide” “reasonable assurance of the safety and effectiveness of the device.”⁴² This gives the impression that the Obtryx is in fact avoidably unsafe—the “special

³⁹ *Ebert*, 2020 WL 2332060, at *10.

⁴⁰ *Id.*

⁴¹ Doc. 50-3.

⁴² 21 U.S.C. § 360c.

controls” serve as the mechanism for making the Obtryx safe.⁴³ The Court, then, denies summary judgment for Boston Scientific on Lavore’s strict liability claims for a design defect and for a failure to warn.

Lavore’s strict liability claim for a manufacturing defect, however, rests on infirm ground. To prove a strict liability claim founded on a manufacturing defect, a plaintiff must show that the product at issue deviated from the manufacturing company’s design specifications.⁴⁴ Lavore here has not claimed or offered any evidence that the specific Obtryx device that was implanted into her differed from other Obtryx units of the same product line, or that “her” specific Obtryx device deviated from Boston Scientific’s design specifications. This compels summary judgment for Boston Scientific on Lavore’s strict liability claim for a manufacturing defect.

D. Lavore’s Breach of Express Warranty Claim

An express warranty is “some form of promise or affirmative statement.” An express warranty can be granted “by any 1) ‘affirmation of fact or promise made by the seller to the buyer which related to the goods,’ 2) ‘description of the

⁴³ Compare with *Burningham v. Wright Med. Tech., Inc.*, 448 P.3d 1283 (Utah 2019) (contrasting Class II against Class III; analyzing Class III medical device under strict liability standards); *Byrnes v. Small*, 60 F. Supp. 3d 1289, 1299 (M.D. Fla. 2015) (stating that a Class III device was, by virtue of being Class III, “incapable of being made safe”).

⁴⁴ See *Zombeck v. Amada Am., Inc.*, No. CIV.A. 06-953, 2009 WL 1423347, at *2 (W.D. Pa. May 20, 2009).

goods’” or 3) ‘sample or model’ that “is part of the basis of the bargain.”’⁴⁵ To create an express warranty, a seller “must expressly communicate the terms of the warranty to the buyer.”⁴⁶

Here, Lavore has not claimed or offered any evidence about any promise, affirmative statement, or express communication that Boston Scientific made. This compels summary judgment for Boston Scientific on Lavore’s breach of express warranty claim.

E. Lavore’s Breach of Implied Warranty Claim

The Master Long Form Complaint specifies that Plaintiffs are asserting a breach of the implied warranty of merchantability.⁴⁷ Federal district courts in Pennsylvania differ on whether to bar these claims as a matter of law when Plaintiffs assert these claims against producers of prescription medical devices.⁴⁸ But the courts that do bar these claims as a categorical matter appear to do so by relying on their prediction that Comment k (described above) would apply to prescription medical devices. As the Court has outlined above, I disagree with this

⁴⁵ *Bowlen v. Coloplast A/S*, No. 2:17CV1372, 2018 WL 4469319, at *5 (W.D. Pa. Sept. 18, 2018), *reconsideration denied*, No. 2:17CV1372, 2019 WL 4597570 (W.D. Pa. Sept. 23, 2019) (internal citations omitted).

⁴⁶ *Goodman v. PPG Industries, Inc.*, 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004).

⁴⁷ See Doc. 56-4 at ¶ 80.

⁴⁸ See *Kline v. Zimmer Holdings, Inc.*, No. CIV.A. 13-513, 2013 WL 3279797, at *7 (W.D. Pa. June 27, 2013) (“Plaintiffs’ claim of breach of the implied warranty of merchantability based upon a manufacturing defect may be maintained”); *compare with* *Burton v. Danek Med., Inc.*, No. CIV.A. 95-5565, 1999 WL 118020, at *7 (E.D. Pa. Mar. 1, 1999) (“This Court also finds that the same reasoning underlying Comment k that excludes prescription drugs from Section 402A should also apply to prescription medical devices. . . . Therefore, prescription medical devices are not covered by Section 402A and Plaintiffs’ strict liability claims must fail.”).

prediction and instead predict that Comment k would not pose a categorical bar. Thus, the Court will not bar Lavore's breach of the implied warranty of merchantability claim as a matter of law. The Court denies summary judgment for Boston Scientific on this claim.

F. Lavore's Fraudulent Concealment Claim

"[T]o the extent that" Lavore "intended to bring a separate claim of fraudulent concealment," Boston Scientific is entitled to summary judgment, because review of Lavore's Short Form Complaint⁴⁹ as well as Plaintiffs' Master Complaint reveals that Lavore has raised "fraudulent concealment only as a safeguard to toll the statute of limitations."⁵⁰

III. CONCLUSION

The Court grants Boston Scientific's motion for summary judgment in part and denies it in part. An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann

Matthew W. Brann

United States District Judge

⁴⁹ See Doc. 50-1.

⁵⁰ *Mubita v. Bos. Sci. Corp.*, No. 2:13-CV-11955, 2015 WL 5838515, at *5 (S.D.W. Va. Oct. 5, 2015); *see also Kilgore v. Boston Scientific Corp.*, No. 2:13-cv-09171, 2015 WL 5838513, at *6 (S.D.W. Va. Oct. 5, 2015).